PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Krivitski & Drost	Atty. Docket: 86017.000010
Serial No.:	09/419,849	Examiner:
Filed:	October 19, 1999	Art Unit:
Title:	METHOD AND APPARATUS TO MEASURE BLOOD FLOW BY AN INTRODUCED VOLUME CHANGE	

Declaration Under 37 C.F.R. §102(d)

Commissioner of Patents and
Trademarks
Washington, D.C. 20231

Sir:

I, Brian B. Shaw, hereby declare as follows:

1. I am a registered patent attorney, Registration No. 33,782 and a partner in the law firm Harter, Secrest & Emery LLP.

2. I am an attorney of record in the above-referenced application, and a copy of the claims as currently pending, and pursuant to a preliminary amendment filed November 1, 2000, are attached as Exhibit A.

3. I have made a rigid comparison of the alleged infringing device (the Transcutaneous Access Blood Flow (TQA) marketed by In-Line Diagnostics set forth in the accompanying declaration of Cornelis J. Drost and the claims of Exhibit A.

4. Based upon this rigid comparison, and as set forth below, it is my opinion, some of the claims are unquestionably infringed.

5. Claim 1 recites in part "A method for determining an initial flow rate of a liquid in a conduit," [Exhibit A, Claim 1]

6. The 510(k) Summary [attached hereto as Exhibit B and identified in the accompanying Drost Declaration hereinafter the "510(k) Summary] states "To claim that the CLM III_{Tqa} can transcutaneously (i.e. through the skin) estimate access blood flow (ABF), which is the rate at which blood is flowing through a dialysis patient's access site."

7. Claim 1 further states "(a) introducing a discrete volume change to the initial flow rate;"

8. The 510(k) Summary states "when this method is used, a 30 cc bolus (10 cc to clear the needle line, 20 cc of actual bolus) of Normal Saline is injected into the arterial line once the optical sensor pad has been properly placed over the access site." [Page 6]

9. The 510(k) Summary states "When this method is used, a 30 cc bolus of normal saline is injected into a veinus port of the dialysis delivery circuit once the optical sensor pad has been properly placed over the access site." [Page 7]

10. Claim 1 states "(b) sensing a corresponding resulting change in the flow in the conduit; and"

11. The 510(k) summary states "the CLM III_{TQA} gathers information about the hematocrit of the blood flowing through the access via an optical sensor that is placed directly over the access shunt of the patient . . . The degree of back scattering and absorption directly effects the amount of light that is reflected back to the detector and is a function of the bulk attenuation co-efficient or "alpha values" of the tissue, blood and skin." [Page 4]

12. The 510(k) Summary states "If the hematocrit of the blood flowing through the access is changed in some manner, (i.e. as a result of a saline bolus being injected into the access site and thereby diluting the access hematocrit) the access site alpha value measured by CLM III_{TQA} sensor will dramatically change." [Page 4]

13. The 510(k) Summary states "By base-lining the alpha value of the access area prior to injecting the bolus, then measuring the change of hematocrit in the access

area as the bolus passes through the access, the CLM III_{TQA} is able to accurately determine the percentage change in hematocrit of the access blood flow." [Page 4]

14. Claim 1 concludes "(c) determining the initial flow rate in response to the introduced volume change and the sensed resulting change."

15. The 510(k) Summary states "Using the FICKE principle and by knowing the volume of the bolus injected into the access and measuring the percentage change in hematocrit, the access blood flow can be directly computed." [Page 4]

16. Therefore, as each of these limitations is directly and literally present in the 510(k) summary, I believe Claim 1 is infringed by the TQA method.

17. Claim 2 depends from Claim 1 and further states "wherein introducing a discrete volume change includes injecting or withdrawing the discrete volume from the conduit."

18. The 510(k) Summary discloses the Arterial Needle Flush Method and the Venous Port Injection method, each of which employ injecting a discrete volume into the conduit (patient access). Therefore, Claim 2 reads on the 510(k) Summary and is infringed.

19. Claim 3 depends from Claim 1 and further recites "further comprising employing one of a flow characteristic sensor and a liquid characteristic sensor." As stated on page 9, lines 9-19 of the present application, "If the liquid characteristics are sensed, the optical, electrical, thermal or material aspects may be sensed. Specifically, the electrical conductivity, optical transmisivity, or temperature, velocity of sound or Doppler frequency."

20. The 510(k) Summary states "The CLM III_{TQA} gathers information about the hematocrit of the blood flowing through the access via an optical sensor that is placed directly over the access shunt of the patient." [Page 4] Therefore, Claim 3 reads on the 510(k) Summary and is infringed.

21. Claim 5 depends from Claim 1 and further recites "wherein sensing the corresponding resulting change includes employing a sensor located at one in the conduit, on the conduit or spaced from an exterior of the conduit."

22. The 510(k) Summary states "The flexibility of the sensor allows it to be placed directly over and on the access area, and allows it to conform to that area, thus

maintaining contact with the skin." [Page 4] Therefore, Claim 5 reads on the system described in the 510(k) Summary and is infringed.

23. Claim 7 depends from Claim 1 and further recites "further comprising sensing the corresponding resulting change in one of a liquid characteristic and a flow characteristic." As stated on page 9, lines 9-19 of the present application, "if the liquid characteristics are sensed, the optical, electrical, thermal or material aspects may be sensed."

24. The 510(k) Summary states "The subject transcutaneous method for estimating access blood flow requires the placement of an optical sensor on the skin directly over the access site in order to detect relative changes in hematocrit occurring in the blood flow. These changes in relative hematocrit occur as a result of the saline bolus, which may be injected into the arterial or venous lines, upstream of the optical sensor." [Page 3] Therefore, Claim 7 reads on the method of the 510(k) Summary and is infringed.

25. Claim 26 recites in part "A method for determining initial blood flow rate in a conduit, comprising:"

26. The 510(k) Summary states "Using the FICKE principle and by knowing the volume of the bolus injected into the access and measuring the percentage change in hematocrit, the access blood flow can be directly computed." [Page 4]

27. Claim 26 further recites "(a) introducing a volume of an indicator into the conduit to create a discrete volume change in the initial flow and a liquid characteristic change in the conduit;"

28. The 510(k) Summary states "When this method is used, a 30 cc bolus of Normal Saline is injected into a venous port of the dialysis deliver circuit once the optical sensor pad has been properly placed over the access site. The venous port is used in this method so that the bolus passes directly into the access . . ." [Page 7] "If the hematocrit of the blood flowing through the access is changed in some manner, (i.e. as a result of a saline bolus being injected into the access site and thereby diluting the access hematocrit), the access site alpha value measured by the CLM III_{TQA} sensor will dramatically change." [Page 4]

29. Claim 26 further recites "(b) optically sensing the liquid characteristic change in the conduit with a sensor located external to the conduit; and"

30. The 510(k) Summary states "the CLM III_{TQA} gathers information about the hematocrit of the blood flowing through the access via an optical sensor that is placed directly over the access shunt of the patient. Light is emitted into the patient's access area from a matrix of light emitting diodes and the back scatter due to the absorption and scattering that light in the tissue is received by detector photo diodes placed at known distances from the LED's." [Page 4]

31. Claim 26 concludes "(c) determining the initial blood flow rate in the conduit in response to the introduced volume of indicator and the sensed liquid characteristic change."

32. The 510(k) Summary states "Using the FICKE principle and by knowing the volume of the bolus injected into the access and measuring the percentage change in hematocrit, the access blood flow can be directly computed." [Page 4]

33. Therefore, as each of the limitations of Claim 26 is directly and literally present in the method of the 510(k) Summary, Claim 26 is infringed.

34. Claim 32 depends from Claim 26 and further recites "wherein the liquid characteristic is blood hematocrit."

35. The 510(k) Summary states "The subject transcutaneous method of estimating access blood flow requires the placement of an optical sensor on the skin directly over the access site in order to detect relative changes in hematocrit occurring in the blood flow. These changes in relative hematocrit occur as a result of a saline bolus which may be injected into the arterial or venous lines, upstream of the optical sensor." [Page 3] As each of these limitations is present in the TQA method described in the 510(k) Summary, Claim 32 is infringed.

36. Therefore, in my opinion, some of the claims of the present application are unquestionably infringed.

I declare that all statements made herein are true and further that these statements were made with the knowledge that willful false statements in the like are so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such false statements may jeopardize the validity of this document and of the patent application to which it relates.

Respectfully Submitted,

Brian B. Shaw

Dated: Feb. 5, 2001